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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,679	11/24/2003	Dmitri Valerjewich Kapoustine	P66870US0	9968

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WASHINGTON, DC 20004

EXAMINER
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MENON, KRISHNAN S

ART UNIT	PAPER NUMBER
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1723

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/18/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/725,679

Applicant(s)

KAPOUSTINE ET AL.

Examiner

Krishnan S. Menon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 12-29,32 and 33 is/are pending in the application.
- 4a) Of the above claim(s) 12-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28,29,32 and 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. 09/868,915.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

Claims 12-29, 32 and 33 are pending, of which 12-27 are withdrawn from consideration as amended 12/21/06.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. No support could be found for the limitation "in the absence of chaotropic substances" of claim 32 in the specification or claims as originally filed.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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1. Claims 28, 29, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kosaka et al (US 4,045,353) in view of EP 0 648 777 A1.

Kosaka (353) teaches a chromatographic composite material as used in the instant claims with a support coated with a cross-linked polymer having fluorine moieties (col 2 lines 40-64). The recitation of the steps for the process of making the composite is not patentable, since the claim is for a process of using the chromatographic composite. Method of use depend on the product, not the process of making the product, unless the applicant can show that the process of making imparts a unique and unobvious structure to the product. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re *Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Claims 28 and 29 are for the process of separating, isolating or purifying (respectively) DNA, RNA, etc by chromatography using the material taught by Kosaka as above. However, Kosaka does not teach chromatographic separation of biomolecules like DNA, etc. EP-777 teaches chromatographic separation of DNA etc using like silica with surface modified to have fluorine moieties (see abstract). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of EP-777 in the teaching of Kosaka to separate DNA etc., because fluorinated surfaces

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are taught as being particularly useful for separation, isolation and purification of DNA from other cellular components by EP-777 (see lines 45-50, page 2), and the process is carried out in one step (see example 2 of EP).

The process of chromatographic separation of DNA and RNA from proteins and other substances also would be inherent in the teaching of Kosaka. Under the principles of inherency, if a prior art device, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art device. When the prior art device is the same as a device described in the specification for carrying out the claimed method, it can be assumed the device will inherently perform the claimed process. In re King, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986).

With respect to claims 32 and 33, the Kosaka reference would be capable of inherently performing the separation as claimed. EP- reference shows the state of the art – that one of ordinary skill in the art would use fluorinated surfaces for DNA-chromatography. Also, EP-077 teaches (page 2 lines 31-34), “as with crushed glass powders, high concentrations of chaotropes are required for adequate binding of the DNA to the Celite [unfluorinated!]”, and further teaches that the invention in EP addresses these problems by fluorination (see page 2 lines 35-50), and “much lower concentrations of chaotropes or alcohols can be utilized to achieve purification of DNA using instant fluorinated surfaces” Page 2 lines 53-56). Thus EP suggests reducing [and therefore, eliminating] use of chaotropes by fluorination.

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2. Claims 28, 29, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kosaka et al (US 4,045,353) in view of EP 0 648 777 A1 and Carstens (US 5,744,257).

Kosaka (353) in view of EP-777 teaches fluorinated monomers like tetrafluoroethylene and vinyl fluoride (Kosaka col 2 lines 4-64) for polymerizing on the support for use in chromatographic separation, isolation and/or purification of biomolecules and the chromatographic separation process, but does not teach fluorination of the polymer. Carstens (257) teaches fluorination using fluorine in nitrogen or XeF<sub>2</sub> (col 3 lines 28-48). It would be obvious to one of ordinary skill in the art at the time of invention to use the teachings of Carstens (257) to fluorinate the surface of the composite material formed with diene type polymers as taught by Kosaka (353) instead of directly polymerizing fluorinated polymers as taught by Kosaka (353) to assure fluorine moieties on the surface for chromatographic separation of organic molecules. One of ordinary skill in the art at the time of invention would chose polymerization of diene type polymers on the support material and then fluorinate as taught by Carstens (257) to obtain the fluorine moieties, instead of polymerizing the fluorinated polymers directly, to improve the strength of the bond between the inorganic material and the fluorinated polymer as taught by Carstens (col 1 lines 4-10) and such strength is required to prevent bleeding of the organic compound and increasing the sample loading as taught by Kosaka (col 1 lines 24-35).

***Response to Arguments***

Applicant's arguments filed 12/21/06 have been fully considered but they are not persuasive.

With respect to the EP reference:

The paragraph quoted from page 3 of the reference in applicant's remarks, page 10 seems to be selective for the sake of the argument. The "Suitable surfaces" emphasized by the applicant is the surface ***before fluorination***, as is clear from the paragraph following the quotation: "... DNA normally binds tightly to the untreated  $\text{Al}(\text{OH})_3$  surface and is retained during elution. The presence of fluorine causes less tight bonding of DNA to the treated  $\text{Al}(\text{OH})_3$  surface ... so that the bound DNA would elute from the fluorinated  $\text{Al}(\text{OH})_3$  surface ..." Therefore, the argument that one would not combine Kosaka with EP because Kosaka teaches high separation ability whereas EP-777 teaches surface that binds but fails to elute DNA is not convincing. However, Kosaka teaches high separation efficiency, and therefore does not require EP-777 as support to show the separation efficiency. EP was used only to show the state of the art that one of ordinary skill in the art would already know and use fluorinated surfaces for chromatographic separation of DNA at the time of invention. Thus the argument is not commensurate in scope with the rejection.

With respect to the argument that EP requires chaotropic agents, again, the paragraphs of the reference (page 2 lines 31-34 and 45-49) are misquoted. What EP teaches is that the surfaces before treatment require high concentrations of chaotropes. After treatment, the concentrations required would be low, as shown in the rejection.

Argument about "not using chaotropic agents" in EP would destroy the reference is also misplaced. It is very clear from the teaching of EP that EP is trying to reduce the use of chaotropic agents. So, how would one destroy the reference when one tried not use any? More over, the reference that can be argued as being modified is Kosaka, not EP. Suggestion from EP, that DNA can be purified using fluorinated surfaces, is being used to modify the Kosaka reference. So, the question of destroying the EP reference is also not commensurate with the scope of the rejection.

In response to applicant's argument that Carstens is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Carstens is at least reasonably pertinent to the problem which applicant was concerned, that is fluorinating surfaces.

Applicant has failed to respond to the inherency part of the rejection of the claims based on the Kosaka reference, and the part of the rejection on the basis that the claims are for the use of a product, the process steps for making the product are not patentable in the use claim.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S. Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 571-272-1151. The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300 for regular communications and (571) 273-8300 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1700.

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1/16/07

Krishnan S Menon  
Primary Examiner  
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